An Act To Amend Sentinel Events Reporting Laws To Reduce Medical Errors and Improve Patient Safety

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §8752, as enacted by PL 2001, c. 678, §1 and affected by §3 and corrected by RR 2001, c. 2, Pt. A, §37 and affected by §38 and amended by PL 2007, c. 324, §17, is further amended to read:

§ 8752. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Division. "Division" means the Department of Health and Human Services, Division of Licensing and Regulatory Services ~~within the Bureau of Medical Services~~.

2. Health care facility. "Health care facility" or "facility" means a state institution as defined under Title 34-B, chapter 1 or a health care facility licensed by the division, except that it does not include a facility licensed as a nursing facility or licensed under chapter ~~1665~~1664. "Health care facility" includes an ambulatory surgical facility, an end-stage renal disease facility, and an intermediate care facility for persons with mental retardation or developmental disabilities.

2-A. Health care facility acquired infection. "Health care facility acquired infection" means an infection acquired in a health care facility by a patient who was admitted for a reason other than that infection and there is no documentation of infection present at the time of admission.

2-B. Immediate jeopardy. "Immediate jeopardy" means a situation in which the provider's noncompliance with one or more requirements of participation in the federal Medicare program has caused, or is likely to cause, serious injury, harm or impairment to or death of a resident.

3. Major permanent loss of function. "Major permanent loss of function" means sensory, motor, physiological or intellectual impairment that ~~requires continued treatment or imposes persistent major restrictions in activities of daily living~~was not present at the time of admission and requires continued treatment or lifestyle change.

3-A. Near miss. A "near miss" is an event or situation that did not produce patient injury, but only because of chance, which may include, but is not limited to, robustness of the patient or a fortuitous, timely intervention.

3-B. Root cause analysis. "Root cause analysis" is a structured process for identifying the causal or contributing factors underlying adverse events. The root cause analysis follows a predefined protocol for identifying these specific factors in causal categories.

4. Sentinel event. ~~"Sentinel event" means:~~

~~A. One of the following that is determined to be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition or that results from the elopement of a hospitalized inpatient who lacks the capacity, as defined in Title 18-A, section 5-801, subsection (c), to make decisions:~~

~~(1) An unanticipated death; or~~

~~(2) A major permanent loss of function that is not present when the patient is admitted to the health care facility;~~

~~B. Surgery on the wrong patient or wrong body part;~~

~~C. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;~~

~~D. Suicide of a patient in a health care facility where the patient receives inpatient care;~~

~~E. Infant abduction or discharge to the wrong family; or~~

~~F. Rape of a patient.~~

4-A. Sentinel event. "Sentinel event" means an unexpected occurrence involving death or a serious physical or psychological injury or a serious reportable event as set out in paragraph E. "Sentinel event" includes the following:

A. An unanticipated death unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility;

B. A major permanent loss of function. A major permanent loss of function that cannot be determined immediately becomes a reportable sentinel event upon the discharge of the patient when the patient has a continued loss of function or upon the elapsing of 2 weeks with the patient having a persistent major loss of function, whichever occurs first;

C. Health care facility acquired infections resulting in death;

D. Any perinatal death or permanent loss of function unrelated to a congenital condition in an infant with a birth weight over 2,500 grams; and

E. Serious reportable events including:

(1) Surgery performed on a wrong body part;

(2) Surgery performed on a wrong patient;

(3) Wrong surgical procedure performed on a patient;

(4) Unintended retention of a foreign object in a patient after surgery or other procedure;

(5) Intraoperative or immediately postoperative death in a patient who was categorized as a normal, healthy patient;

(6) Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the health care facility;

(7) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended;

(8) Patient death or serious disability associated with intravascular air embolism that occurs while the patient is being cared for in a health care facility;

(9) Infant discharged to the wrong person;

(10) Patient death or serious disability associated with patient leaving the facility without permission;

(11) Patient suicide or attempted suicide resulting in serious disability while the patient is being cared for in a health care facility;

(12) Patient death or serious disability associated with a medication error;

(13) Patient death or serious disability associated with a hemolytic reaction due to the administration of incompatible blood or blood products;

(14) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while the patient is being cared for in a health care facility;

(15) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility;

(16) Death or serious disability associated with failure to identify and treat hyperbilirubinemia in a newborn while the patient is being cared for in a health care facility;

(17) Stage 3 or 4 pressure ulcers acquired after admission to a health care facility;

(18) Patient death or serious disability due to spinal manipulative therapy;

(19) Artificial insemination or fertilization with the wrong donor sperm or wrong egg;

(20) Patient death or serious disability associated with an electric shock while the patient is being cared for in a health care facility;

(21) An incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

(22) Patient death or serious disability associated with a burn from any source that occurred while the patient is being cared for in a health care facility;

(23) Patient death or serious disability associated with a fall that occurred while the patient is being cared for in a health care facility;

(24) Patient death or serious disability associated with the use of restraints or bedrails while the patient is being cared for in a health care facility;

(25) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider;

(26) Abduction of a patient of any age;

(27) Sexual assault on a patient within or on the grounds of a health care facility; and

(28) Death or significant injury of a patient resulting from a physical assault that occurs within or on the grounds of a health care facility.

Sec. 2. 22 MRSA §8753, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

§ 8753. Mandatory reporting of sentinel events

A health care facility shall report to the division ~~a sentinel event that occurs to a patient while the patient is in the health care facility as provided in this section~~whenever it has reason to believe that a suspected sentinel event or a sentinel event has occurred, as provided in this chapter.

1. Notification. A health care facility shall notify the division of ~~the occurrence of~~a suspected sentinel event or a sentinel event by the next business day after the ~~sentinel~~ event has occurred or the next business day after the facility ~~determines~~discovers that the event occurred. If the patient requires transfer from one health care facility to another health care facility, both the sending and receiving facilities shall notify the division of a suspected sentinel event or a sentinel event by the next business day after the event has occurred or the next business day after the facility discovers that the event occurred. The notification must include the date and time of notification, the name of the health care facility and the type of sentinel event pursuant to section 8752, subsection ~~44~~-A.

2. Reporting. ~~A~~The health care facility where the sentinel event occurred shall file a written report no later than 45 days following the notification of the occurrence of a suspected sentinel event or a sentinel event pursuant to subsection 1. The written report must be signed by the chief executive officer of the facility and must contain the following information:

A. Facility name and address;

B. Name, title and phone number of the contact person for the facility;

C. The date and time of the sentinel event;

D. The type of sentinel event and a brief description of the sentinel event; and

~~E. Identification of clinical and organizational systems or processes that may have contributed to the sentinel event;~~

~~F. Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and~~

~~G. A brief description of any corrective action taken or planned.~~

H. A thorough and credible root cause analysis. A root cause analysis is thorough and credible only in accordance with subparagraphs (1) and (2).

(1) A thorough root cause analysis must include a determination of the human and other factors most directly associated with the sentinel event and the processes and systems related to its occurrence; an analysis of the underlying systems and processes to determine where redesign might reduce risk; an inquiry into all areas appropriate to the specific type of event; an identification of risk points and their potential contributions to the event; a determination of potential improvement in processes or systems that would tend to decrease the likelihood of such an event in the future, or a determination, after analysis, that no such improvement

opportunities exist; and an action plan that identifies changes that can be implemented, who is responsible for implementation, when the action will be implemented and how the effectiveness of the action will be evaluated.

(2) A credible root cause analysis must include participation by the leadership of the health care facility and by the individuals most closely involved in the processes and systems under review, is internally consistent without contradictions or unanswered questions, provides an explanation for all findings of "not applicable" or "no problem" and includes consideration of any relevant literature.

3. Cooperation. A health care facility that has filed a notification or a report of the occurrence of a sentinel event under this section shall cooperate with the division as necessary for the division to fulfill its duties under section 8754.

4. Immunity. A person who in good faith reports a suspected sentinel event or a sentinel event, provides a root cause analysis or expresses regret or an apology to the patient, or family or other individual pursuant to this chapter is immune from any civil or criminal liability for the act of reporting or participating in the review by the division. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. This subsection may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

5. Near miss notification. A health care facility may notify the division of the occurrence of a near miss. Should a facility report a near miss, the notification must include the date and time of notification, the name of the health care facility and the type of event or situation pursuant to section 8752, subsection 4-A that is related to the near miss.

Sec. 3. 22 MRSA §8753-A is enacted to read:

§ 8753-A. Standardized procedure

A health care facility shall follow a standardized procedure for the identification, notification and reporting requirements under this chapter. The division shall develop the standardized procedure by adoption of routine technical rules under Title 5, chapter 375, subchapter 2-A.

Sec. 4. 22 MRSA §8753-B is enacted to read:

§ 8753-B. Expression of regret

An individual expression of regret or apology to the patient or family or other individual regarding an adverse event that is provided within 14 days after the event is discovered does not constitute a legal admission of liability and is inadmissible in a civil or administrative proceeding, including an arbitration or mediation proceeding. An individual expression of regret or apology may not be examined in any deposition or civil or administrative proceeding.

Sec. 5. 22 MRSA §8754, sub-§1, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

1. Initial review; other action. Upon receipt of a notification or report of a suspected sentinel event or a sentinel event, the division shall complete an initial review and may take such other action as the division determines to be appropriate under applicable rules and within the jurisdiction of the division. The division may conduct on-site reviews of medical records and may retain the services of consultants when necessary to the division.

A. The division may conduct on-site visits to health care facilities to determine compliance with this chapter.

B. Division personnel responsible for sentinel event oversight shall report potential immediate jeopardy to the licensing section of the division.

Sec. 6. 22 MRSA §8754, sub-§1-A is enacted to read:

1-A. Determination. The division is responsible for determining the reportability of sentinel events.

Sec. 7. 22 MRSA §8754, sub-§3, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

3. Confidentiality. Notifications and reports ~~of sentinel events~~ filed pursuant to this chapter and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.

A. Privileged and confidential information under this subsection is not:

(1) Subject to public access under Title 1, chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;

(2) Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or

(3) Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

B. The transfer of any information to which this chapter applies by a health care facility to the division or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established under this chapter or other laws of this State.

C. The division shall take appropriate measures to protect the security of any information to which this chapter applies.

D. This section may not be construed to limit other privileges that are available under federal law or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this subsection.

E. For the purposes of this subsection, "privileged and confidential information" does not include:

(1) Any final administrative action;

(2) Information independently received pursuant to a 3rd-party complaint investigation conducted pursuant to department rules; or

(3) Information designated as confidential under rules and laws of this State.

F. Records preceding a final administrative action are privileged and confidential under this chapter.

This subsection does not affect the obligations of the department relating to federal law.

Sec. 8. 22 MRSA §8755, as enacted by PL 2001, c. 678, §1 and affected by §3, is repealed and the following enacted in its place:

§ 8755. Compliance

1. Civil penalty. When the division makes a determination that a health care facility violated any provision of this chapter or rules adopted pursuant to this chapter, the health care facility is subject to a civil penalty payable to the State of not more than $25,000 per unreported sentinel event. Funds collected pursuant to this section must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

2. Appeal. To appeal the imposition of a penalty under this section, a health care facility must submit to the division a written request for an administrative hearing within 10 days of notice of imposition of a penalty pursuant to this section.

3. Injunction. Notwithstanding any other remedies provided by law, the Office of the Attorney General may seek an injunction to require compliance with the provisions of this chapter.

4. Enforcement. The Office of the Attorney General may file a complaint with the District Court seeking injunctive relief for violations of this chapter.

SUMMARY

This bill defines additional terms in the law dealing with sentinel event reporting, including "health care facility acquired infection," "immediate jeopardy," "near miss" and "root cause analysis." This bill also amends the definition of "sentinel event." It also adds a list of serious reportable events derived from a publication of the National Quality Forum.

This bill requires health care facilities to report suspected sentinel events as well as sentinel events.

This bill also requires hospitals to follow a standardized procedure for the identification, notification and reporting requirements.

This bill allows health care facilities to voluntarily notify the Department of Health and Human Services, Division of Licensing and Regulatory Services of the occurrence of a near miss.

This bill gives immunity to a person who in good faith reports a suspected sentinel event or a sentinel event, or expresses regret or an apology to the patient or the patient's family.

This bill increases the civil penalty to no more than $25,000, instead of $5,000, authorizes the division to collect the civil penalty without going to court and gives the health care facility the right to request an administrative hearing to contest the imposition of a penalty.

This bill provides injunctive relief to require compliance with the sentinel events reporting law.